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(54) **MEDICAL IMPLANT**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,334,629	A	8/1967	Colm
3,834,394	A	9/1974	Hunter et al.
4,085,757	A	4/1978	Pevsner
4,282,875	A	8/1981	Serbinenko et al.
4,311,146	A	1/1982	Wonder
4,327,734	A	5/1982	White, Jr.
4,341,218	A	7/1982	U
4,346,712	A	8/1982	Handa et al.
4,364,392	A	12/1982	Strother et al.
4,402,319	A	9/1983	Handa et al.
4,441,495	A	4/1984	Hicswa
4,494,531	A	1/1985	Gianturco
4,517,979	A	5/1985	Pecenka
4,545,367	A	10/1985	Tucci
4,638,803	A	1/1987	Rand

(Continued)

FOREIGN PATENT DOCUMENTS

CA	2144725	5/1994
CA	2265062	9/1999

(Continued)

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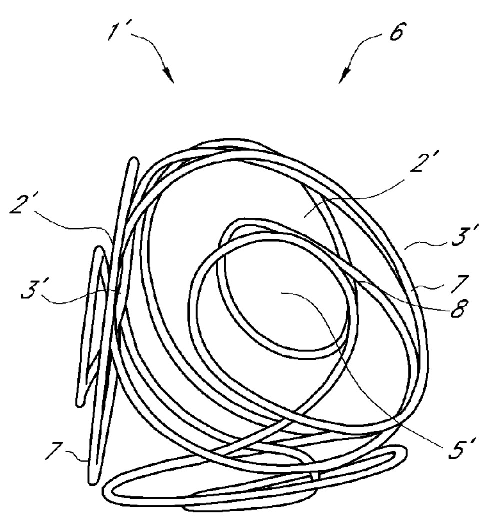
(57) **ABSTRACT**

The invention relates to a medical implant in the form of an elongated helix wherein at least one part of the helix is preformed in such a manner that it has a secondary structure of identically sized loops which it assumes during implantation at the placement site, with said structure in turn forming at the placement site during implantation a polyhedral tertiary structure, and the polyhedron being provided with at least one additional loop.

20 Claims, 8 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

4,719,924	A	1/1988	Crittenden et al.
4,735,201	A	4/1988	O'Reilly
4,745,919	A	5/1988	Bundy et al.
4,781,177	A	11/1988	Lebigot
4,787,899	A	11/1988	Lazarus
4,819,637	A	4/1989	Dormandy, Jr. et al.
4,832,055	A	5/1989	Palestrant
4,932,419	A	6/1990	de Toledo
4,944,746	A	7/1990	Iwata et al.
4,957,501	A	9/1990	Lahille et al.
4,990,155	A	2/1991	Wilkoff
4,994,069	A	2/1991	Ritchart et al.
5,002,556	A	3/1991	Ishida et al.
5,026,377	A	6/1991	Burton et al.
5,035,706	A	7/1991	Giantureo et al.
5,037,427	A	8/1991	Harada et al.
5,062,829	A	11/1991	Pryor et al.
5,104,399	A	4/1992	Lazarus
5,108,407	A	4/1992	Geremia et al.
5,109,867	A	5/1992	Twyford, Jr.
5,122,136	A	6/1992	Guglielmi et al.
5,133,731	A	7/1992	Butler et al.
5,133,732	A	7/1992	Wiktor
5,147,370	A	9/1992	McNamara et al.
5,167,624	A	12/1992	Butler et al.
5,181,921	A	1/1993	Makita et al.
5,192,301	A	3/1993	Kamiya et al.
5,211,658	A	5/1993	Clouse
5,217,484	A	6/1993	Marks
5,222,970	A	6/1993	Reeves
5,224,953	A	7/1993	Morgentaler
5,226,911	A	7/1993	Chee et al.
5,234,437	A	8/1993	Sepetka
5,250,071	A	10/1993	Palermo
5,256,146	A	10/1993	Ensminger et al.
5,261,916	A	11/1993	Engelson
5,263,964	A	11/1993	Purdy
5,304,194	A	4/1994	Chee et al.
5,304,195	A	4/1994	Twyford, Jr. et al.
5,312,415	A	5/1994	Palermo
5,314,472	A	5/1994	Fontaine
5,334,210	A	8/1994	Gianturco
5,350,397	A	9/1994	Palermo et al.
5,354,295	A	10/1994	Guglielmi et al.
5,368,592	A	11/1994	Stern et al.
5,382,259	A	1/1995	Phelps et al.
5,382,260	A	1/1995	Dormandy, Jr. et al.
5,382,261	A	1/1995	Palmaz
5,397,345	A	3/1995	Lazarus
5,417,708	A	5/1995	Hall et al.
5,423,829	A	6/1995	Pham et al.
5,423,849	A	6/1995	Engelson et al.
5,443,454	A	8/1995	Tanabe et al.
5,443,478	A	8/1995	Purdy
5,456,693	A	10/1995	Conston et al.
5,476,472	A	12/1995	Dormandy, Jr. et al.
5,480,382	A	1/1996	Hammerslag et al.
5,498,227	A	3/1996	Mawad
5,507,769	A	4/1996	Marin et al.
5,522,822	A	6/1996	Phelps et al.
5,522,836	A	6/1996	Palermo
5,527,338	A	6/1996	Purdy
5,536,274	A	7/1996	Neuss
5,540,680	A	7/1996	Guglielmi et al.
5,549,624	A	8/1996	Mirigian et al.
5,556,426	A	9/1996	Popadiuk et al.
5,562,698	A	10/1996	Parker
5,569,245	A	10/1996	Guglielmi et al.
5,573,520	A	11/1996	Schwartz et al.
5,578,074	A	11/1996	Mirigian
5,582,619	A	12/1996	Ken
5,601,600	A	2/1997	Ton
5,624,449	A	4/1997	Pham et al.
5,624,461	A	4/1997	Mariant
5,626,599	A	5/1997	Bourne et al.
5,634,928	A	6/1997	Fischell et al.
5,639,277	A	6/1997	Mariant et al.
5,643,254	A	7/1997	Scheldrup et al.
5,645,558	A	7/1997	Horton
5,645,564	A	7/1997	Northrup et al.
5,649,949	A	7/1997	Wallace et al.
5,658,308	A	8/1997	Snyder
5,662,700	A	9/1997	Lazarus
5,669,905	A	9/1997	Scheldrup et al.
5,669,931	A	9/1997	Kupiecki et al.
5,690,666	A	11/1997	Berenstein et al.
5,690,667	A	11/1997	Gia
5,690,671	A	11/1997	McGurk et al.
5,693,067	A	12/1997	Purdy
5,695,517	A	12/1997	Marin et al.
5,700,258	A	12/1997	Mirigian et al.
5,702,361	A	12/1997	Evans et al.
5,718,711	A	2/1998	Berenstein et al.
5,725,534	A	3/1998	Rasmussen
5,725,546	A	3/1998	Samson
5,725,552	A	3/1998	Kotula et al.
5,733,329	A	3/1998	Wallace et al.
5,743,905	A	4/1998	Eder et al.
5,746,734	A	5/1998	Dormandy, Jr. et al.
5,746,769	A	5/1998	Ton et al.
5,749,891	A	5/1998	Ken et al.
5,749,894	A	5/1998	Engelson
5,749,918	A	5/1998	Hogendijk et al.
5,759,161	A	6/1998	Ogawa et al.
5,766,219	A	6/1998	Horton
5,797,953	A	8/1998	Tekulve
5,800,426	A	9/1998	Taki et al.
5,800,453	A	9/1998	Gia
5,800,454	A	9/1998	Jacobsen et al.
5,800,455	A	9/1998	Palermo et al.
5,814,062	A	9/1998	Sepetka et al.
5,830,230	A	11/1998	Berryman et al.
5,833,705	A	11/1998	Ken et al.
5,843,118	A	12/1998	Sepetka et al.
5,846,210	A	12/1998	Ogawa et al.
5,851,206	A	12/1998	Guglielmi et al.
5,853,418	A	12/1998	Ken et al.
5,855,578	A	1/1999	Guglielmi et al.
5,891,058	A	4/1999	Taki et al.
5,891,128	A	4/1999	Gia et al.
5,891,130	A	4/1999	Palermo et al.
5,891,155	A	4/1999	Irie
5,891,192	A	4/1999	Murayama et al.
5,895,385	A	4/1999	Guglielmi et al.
5,895,391	A	4/1999	Farnholtz
5,895,410	A	4/1999	Forber et al.
5,895,411	A	4/1999	Irie
5,911,731	A	6/1999	Pham et al.
5,911,737	A	6/1999	Lee et al.
5,916,235	A	6/1999	Guglielmi
5,919,187	A	7/1999	Guglielmi et al.
5,925,037	A	7/1999	Guglielmi et al.
5,925,059	A	7/1999	Palermo et al.
5,925,060	A	7/1999	Forber
5,925,062	A	7/1999	Purdy
5,928,226	A	7/1999	Guglielmi et al.
5,935,145	A	8/1999	Villar et al.
5,935,148	A	8/1999	Villar et al.
5,941,249	A	8/1999	Maynard
5,941,888	A	8/1999	Wallace et al.
5,944,714	A	8/1999	Guglielmi et al.
5,944,733	A	8/1999	Engelson
5,947,962	A	9/1999	Guglielmi et al.
5,947,963	A	9/1999	Guglielmi
5,957,948	A	9/1999	Mariant
5,964,797	A	10/1999	Ho
5,972,019	A	10/1999	Engelson et al.
5,976,126	A	11/1999	Guglielmi
5,976,131	A	11/1999	Guglielmi et al.
5,976,152	A	11/1999	Regan et al.
5,976,162	A	11/1999	Doan et al.
5,980,514	A	11/1999	Kupiecki et al.
5,980,550	A	11/1999	Eder et al.
5,980,554	A	11/1999	Lenker et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,984,929	A	11/1999	Bashiri et al.
5,984,944	A	11/1999	Forber
5,989,242	A	11/1999	Saadat et al.
6,001,092	A	12/1999	Mirigian et al.
6,004,338	A	12/1999	Ken et al.
6,010,498	A	1/2000	Guglielmi
6,013,084	A	1/2000	Ken et al.
6,015,424	A	1/2000	Rosenbluth et al.
6,017,364	A	1/2000	Lazarus
6,017,977	A	1/2000	Evans et al.
6,019,757	A	2/2000	Scheldrup
6,019,779	A	2/2000	Thorud et al.
6,022,369	A	2/2000	Jacobsen et al.
6,024,754	A	2/2000	Engelson
6,024,765	A	2/2000	Wallace et al.
6,030,413	A	2/2000	Lazarus
6,033,423	A	3/2000	Ken et al.
6,039,749	A	3/2000	Marin et al.
6,056,770	A	5/2000	Epstein et al.
6,059,779	A	5/2000	Mills
6,059,815	A	5/2000	Lee et al.
6,063,070	A	5/2000	Eder
6,063,100	A	5/2000	Diaz et al.
6,063,104	A	5/2000	Villar et al.
6,066,133	A	5/2000	Guglielmi et al.
6,066,149	A	5/2000	Samson et al.
6,068,644	A	5/2000	Lulo et al.
6,074,407	A	6/2000	Levine et al.
6,077,260	A	6/2000	Wheelock et al.
D427,680	S	7/2000	Mariant et al.
6,083,220	A	7/2000	Guglielmi et al.
6,086,577	A	7/2000	Ken et al.
6,090,125	A	7/2000	Horton
6,093,199	A	7/2000	Brown et al.
6,096,034	A	8/2000	Kupiecki et al.
6,096,546	A	8/2000	Raskin
6,102,917	A	8/2000	Maitland et al.
6,102,932	A	8/2000	Kurz
6,102,933	A	8/2000	Lee et al.
6,113,622	A	9/2000	Hieshima
6,117,142	A	9/2000	Goodson et al.
6,117,157	A	9/2000	Tekulve
6,123,714	A	9/2000	Gia et al.
6,126,672	A	10/2000	Berryman et al.
6,136,015	A	10/2000	Kurz et al.
6,143,007	A	11/2000	Mariant et al.
6,146,373	A	11/2000	Cragg et al.
6,149,664	A	11/2000	Kurz
6,149,681	A	11/2000	Houser et al.
6,156,061	A	12/2000	Wallace et al.
6,159,165	A	12/2000	Ferrera et al.
6,159,206	A	12/2000	Ogawa
6,165,178	A	12/2000	Bashiri et al.
6,165,193	A	12/2000	Greene, Jr. et al.
6,165,198	A	12/2000	McGurk et al.
6,168,570	B1	1/2001	Ferrera
6,168,592	B1	1/2001	Kupiecki et al.
6,168,610	B1	1/2001	Marin et al.
6,168,615	B1	1/2001	Ken et al.
6,168,622	B1	1/2001	Mazzocchi
6,171,326	B1	1/2001	Ferrera et al.
6,183,491	B1	2/2001	Lulo
6,183,495	B1	2/2001	Lenker et al.
6,187,024	B1	2/2001	Boock et al.
6,187,027	B1	2/2001	Mariant et al.
6,190,373	B1	2/2001	Palermo et al.
6,193,708	B1	2/2001	Ken et al.
6,193,728	B1	2/2001	Ken et al.
RE37,117	E	3/2001	Palermo
6,202,261	B1	3/2001	Moore et al.
6,203,547	B1	3/2001	Nguyen et al.
6,221,066	B1	4/2001	Ferrera et al.
6,221,086	B1	4/2001	Forber
6,224,610	B1	5/2001	Ferrera
6,231,573	B1	5/2001	Amor et al.
6,231,586	B1	5/2001	Mariant
6,231,590	B1	5/2001	Slaikeu et al.
6,231,597	B1	5/2001	Deem et al.
6,238,403	B1	5/2001	Greene, Jr. et al.
6,238,415	B1	5/2001	Sepetka et al.
6,241,691	B1	6/2001	Ferrera et al.
6,254,592	B1	7/2001	Samson et al.
6,270,495	B1	8/2001	Palermo
6,277,125	B1	8/2001	Barry et al.
6,277,126	B1	8/2001	Barry et al.
6,280,457	B1	8/2001	Wallace et al.
6,281,263	B1	8/2001	Evans et al.
6,287,315	B1	9/2001	Wijeratne et al.
6,287,318	B1	9/2001	Villar et al.
6,293,960	B1	9/2001	Ken
6,296,622	B1	10/2001	Kurz et al.
6,299,619	B1	10/2001	Greene, Jr. et al.
6,299,627	B1	10/2001	Eder et al.
6,306,153	B1	10/2001	Kurz et al.
6,312,405	B1	11/2001	Meyer et al.
6,312,421	B1	11/2001	Boock
6,315,709	B1	11/2001	Garibaldi et al.
6,319,267	B1	11/2001	Kurz
6,322,576	B1	11/2001	Wallace et al.
6,328,750	B1	12/2001	Berry et al.
6,331,184	B1	12/2001	Abrams
6,335,384	B1	1/2002	Evans et al.
6,338,736	B1	1/2002	Boosfeld et al.
6,344,041	B1	2/2002	Kupiecki et al.
6,344,048	B1	2/2002	Chin et al.
6,346,091	B1	2/2002	Jacobsen et al.
6,346,117	B1	2/2002	Greenhalgh
6,348,041	B1	2/2002	Klint
6,361,547	B1	3/2002	Hieshima
6,364,823	B1	4/2002	Garibaldi et al.
6,368,338	B1	4/2002	Konya et al.
6,371,972	B1	4/2002	Wallace et al.
6,375,606	B1	4/2002	Garibaldi et al.
6,375,628	B1	4/2002	Zadno-Azizi et al.
6,375,668	B1	4/2002	Gifford et al.
6,375,669	B1	4/2002	Rosenbluth et al.
6,379,329	B1	4/2002	Naglreiter et al.
6,379,374	B1	4/2002	Hieshima et al.
6,383,146	B1	5/2002	Klint
6,383,174	B1	5/2002	Eder
6,383,204	B1	5/2002	Ferrera et al.
6,383,205	B1	5/2002	Samson et al.
6,409,721	B1	6/2002	Wheelock et al.
6,416,535	B1	7/2002	Lazarus
6,416,541	B2	7/2002	Denardo
6,423,085	B1	7/2002	Murayama et al.
6,425,893	B1	7/2002	Guglielmi
6,425,914	B1	7/2002	Wallace et al.
6,428,557	B1	8/2002	Hilaire
6,428,558	B1	8/2002	Jones et al.
6,454,780	B1	9/2002	Wallace
6,458,119	B1	10/2002	Berenstein et al.
6,458,127	B1	10/2002	Truckai et al.
6,458,137	B1	10/2002	Klint
6,464,699	B1	10/2002	Swanson
6,468,266	B1	10/2002	Bashiri et al.
6,475,169	B2	11/2002	Ferrera
6,475,227	B2	11/2002	Burke et al.
6,478,773	B1	11/2002	Gandhi et al.
6,485,524	B2	11/2002	Strecker
6,494,884	B2	12/2002	Gifford, III et al.
6,500,149	B2	12/2002	Gandhi et al.
6,500,190	B2	12/2002	Greene, Jr. et al.
6,506,204	B2	1/2003	Mazzocchi
6,511,468	B1	1/2003	Cragg et al.
6,514,264	B1	2/2003	Naglreiter
6,530,934	B1	3/2003	Jacobsen et al.
6,533,801	B2	3/2003	Wallace et al.
6,537,293	B1	3/2003	Berryman et al.
6,540,657	B2	4/2003	Cross, III et al.
6,544,163	B2	4/2003	Wallace et al.
6,544,225	B1	4/2003	Lulo et al.
6,544,268	B1	4/2003	Lazarus
6,544,275	B1	4/2003	Teoh

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,547,804	B2	4/2003	Porter et al.	
6,551,305	B2	4/2003	Ferrera et al.	
6,551,340	B1	4/2003	Konya et al.	
6,554,849	B1	4/2003	Jones et al.	
6,558,367	B1	5/2003	Cragg et al.	
6,569,179	B2	5/2003	Teoh et al.	
6,572,628	B2	6/2003	Dominguez et al.	
6,575,994	B1	6/2003	Marin et al.	
6,585,748	B1	7/2003	Jeffree	
6,585,754	B2	7/2003	Wallace et al.	
6,589,227	B2	7/2003	Klint	
6,589,230	B2	7/2003	Gia et al.	
6,589,236	B2	7/2003	Wheelock et al.	
6,589,265	B1	7/2003	Palmer et al.	
6,592,605	B2	7/2003	Lenker et al.	
6,602,261	B2	8/2003	Greene, Jr. et al.	
6,602,269	B2	8/2003	Wallace et al.	
6,603,994	B2	8/2003	Wallace et al.	
6,605,101	B1	8/2003	Schaefer et al.	
6,607,538	B1	8/2003	Ferrera et al.	
6,607,539	B1	8/2003	Hayashi et al.	
6,610,085	B1	8/2003	Lazarus	
6,613,074	B1	9/2003	Mitelberg et al.	
6,616,617	B1 *	9/2003	Ferrera et al.	600/585
6,620,152	B2	9/2003	Guglielmi	
6,623,493	B2	9/2003	Wallace et al.	
6,632,241	B1	10/2003	Hancock et al.	
6,635,068	B1	10/2003	Dubrul et al.	
6,635,069	B1	10/2003	Teoh et al.	
6,638,291	B1	10/2003	Ferrera et al.	
6,638,293	B1	10/2003	Makower et al.	
6,656,173	B1	12/2003	Palermo	
6,656,201	B2	12/2003	Ferrera et al.	
6,656,218	B1	12/2003	Denardo et al.	
6,656,351	B2	12/2003	Boyle	
6,660,020	B2	12/2003	Wallace et al.	
6,663,607	B2	12/2003	Slaikeu et al.	
6,679,903	B2	1/2004	Kurz	
6,685,653	B2	2/2004	Ehr et al.	
6,685,696	B2	2/2004	Fleischhacker et al.	
6,689,141	B2	2/2004	Ferrera et al.	
6,692,510	B2	2/2004	West	
6,702,844	B1	3/2004	Lazarus	
6,716,238	B2	4/2004	Elliott	
6,723,112	B2	4/2004	Ho et al.	
6,743,236	B2	6/2004	Barry et al.	
6,743,251	B1	6/2004	Eder	
6,767,358	B2	7/2004	Leonhardt et al.	
6,811,561	B2	11/2004	Diaz et al.	
6,814,748	B1	11/2004	Baker et al.	
6,835,185	B2	12/2004	Ramzipoor et al.	
6,849,081	B2	2/2005	Sepetka et al.	
6,852,116	B2	2/2005	Leonhardt et al.	
6,853,418	B2	2/2005	Suzuki et al.	
6,855,153	B2	2/2005	Saadat	
6,855,155	B2	2/2005	Denardo et al.	
6,860,893	B2	3/2005	Wallace et al.	
6,860,901	B1	3/2005	Baker et al.	
6,872,218	B2	3/2005	Ferrera et al.	
6,878,163	B2	4/2005	Denardo et al.	
6,905,503	B2	6/2005	Gifford, III et al.	
6,913,618	B2	7/2005	Denardo et al.	
6,929,654	B2	8/2005	Teoh et al.	
6,945,956	B2	9/2005	Waldhauser et al.	
6,958,061	B2	10/2005	Truckai et al.	
6,958,068	B2	10/2005	Hieshima	
6,964,657	B2	11/2005	Cragg et al.	
6,966,892	B2	11/2005	Gandhi et al.	
6,984,240	B1	1/2006	Ken et al.	
6,994,711	B2	2/2006	Hieshima et al.	
7,014,645	B2	3/2006	Greene, Jr. et al.	
7,029,486	B2	4/2006	Schaefer et al.	
7,029,487	B2	4/2006	Greene, Jr. et al.	
7,033,374	B2	4/2006	Schaefer et al.	
7,058,456	B2	6/2006	Pierce	
7,060,083	B2	6/2006	Gerberding	
7,070,607	B2	7/2006	Murayama et al.	
7,147,618	B2	12/2006	Kurz	
7,169,161	B2	1/2007	Bonnette et al.	
7,182,774	B2	2/2007	Barry et al.	
7,198,613	B2	4/2007	Gandhi et al.	
7,238,194	B2	7/2007	Monstadt et al.	
7,300,458	B2	11/2007	Henkes et al.	
7,316,701	B2	1/2008	Ferrera et al.	
7,323,000	B2	1/2008	Monstdt et al.	
7,331,973	B2	2/2008	Gesswein et al.	
7,344,558	B2	3/2008	Lorenzo et al.	
7,410,482	B2	8/2008	Murphy et al.	
7,473,266	B2	1/2009	Glaser	
7,485,122	B2	2/2009	Teoh	
7,485,317	B1	2/2009	Murayama et al.	
7,524,322	B2	4/2009	Monstdt et al.	
7,575,582	B2	8/2009	Gandhi et al.	
7,578,826	B2	8/2009	Gandhi et al.	
RE41,029	E	12/2009	Guglielmi et al.	
7,691,124	B2	4/2010	Balgobin	
7,708,755	B2	5/2010	Davis, III et al.	
7,722,636	B2	5/2010	Farnan	
7,722,637	B2	5/2010	Barry et al.	
7,766,933	B2	8/2010	Davis, III et al.	
7,811,305	B2	10/2010	Balgobin et al.	
7,841,994	B2	11/2010	Skujins et al.	
7,879,064	B2	2/2011	Monstadt et al.	
7,883,526	B2	2/2011	Jones et al.	
7,896,899	B2	3/2011	Patterson et al.	
7,901,444	B2	3/2011	Slazas	
7,901,704	B2	3/2011	Richard	
7,918,872	B2	4/2011	Mitelberg et al.	
7,938,845	B2	5/2011	Aganon et al.	
7,955,272	B2	6/2011	Rooney et al.	
8,002,789	B2	8/2011	Ramzipoor et al.	
8,007,509	B2	8/2011	Buiser et al.	
8,372,110	B2	2/2013	Monstadt et al.	
2002/0010481	A1	1/2002	Jayaraman	
2002/0019647	A1 *	2/2002	Wallace et al.	606/200
2002/0052613	A1	5/2002	Ferrera et al.	
2002/0065529	A1	5/2002	Laurent et al.	
2002/0072712	A1	6/2002	Nool et al.	
2002/0072791	A1	6/2002	Eder et al.	
2002/0082620	A1	6/2002	Lee	
2002/0087184	A1	7/2002	Eder et al.	
2002/0120297	A1	8/2002	Shadduck	
2002/0128671	A1	9/2002	Wallace et al.	
2002/0138095	A1	9/2002	Mazzocchi et al.	
2002/0143349	A1	10/2002	Gifford et al.	
2002/0169473	A1	11/2002	Sepetka et al.	
2003/0014073	A1	1/2003	Bashiri et al.	
2003/0040733	A1	2/2003	Cragg et al.	
2003/0045901	A1	3/2003	Opolski	
2003/0083676	A1	5/2003	Wallace	
2003/0130689	A1	7/2003	Wallace et al.	
2003/0169473	A1	9/2003	Cotter et al.	
2003/0176857	A1	9/2003	Lee	
2003/0181927	A1	9/2003	Wallace	
2003/0216772	A1	11/2003	Konya et al.	
2003/0225365	A1	12/2003	Greff et al.	
2004/0002731	A1	1/2004	Aganon et al.	
2004/0002732	A1	1/2004	Teoh et al.	
2004/0002733	A1	1/2004	Teoh	
2004/0006354	A1	1/2004	Schaefer et al.	
2004/0006362	A1	1/2004	Schaefer et al.	
2004/0006363	A1	1/2004	Schaefer	
2004/0024394	A1	2/2004	Wallace et al.	
2004/0034363	A1	2/2004	Wilson et al.	
2004/0034378	A1	2/2004	Monstadt et al.	
2004/0045554	A1	3/2004	Schaefer et al.	
2004/0078050	A1	4/2004	Monstadt et al.	
2004/0082879	A1	4/2004	Klint	
2004/0106946	A1	6/2004	Ferrera et al.	
2004/0181256	A1	9/2004	Glaser	
2004/0193178	A1	9/2004	Nikolchev	
2004/0193206	A1	9/2004	Gerberding et al.	
2004/0220563	A1	11/2004	Eder	
2004/0220585	A1	11/2004	Nikolchev	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2004/0225279	A1	11/2004	Raymond
2004/0236344	A1	11/2004	Monstadt et al.
2004/0260384	A1	12/2004	Allen
2005/0021023	A1	1/2005	Guglielmi et al.
2005/0021074	A1	1/2005	Elliott
2005/0079196	A1	4/2005	Henkes et al.
2005/0171572	A1	8/2005	Martinez
2005/0177185	A1	8/2005	Becker et al.
2005/0187564	A1	8/2005	Jayaraman
2006/0025801	A1	2/2006	Lulo et al.
2006/0025802	A1	2/2006	Sowers
2006/0036281	A1	2/2006	Patterson et al.
2006/0079926	A1	4/2006	Desai et al.
2006/0106417	A1	5/2006	Tessmer et al.
2006/0116711	A1	6/2006	Elliott et al.
2006/0116714	A1	6/2006	Sepetka et al.
2006/0200190	A1	9/2006	Lorenzo et al.
2006/0271097	A1	11/2006	Ramzipoor et al.
2006/0276824	A1	12/2006	Mitelberg et al.
2007/0055302	A1	3/2007	Henry et al.
2007/0083226	A1	4/2007	Buiser et al.
2007/0142893	A1	6/2007	Buiser et al.
2007/0150045	A1	6/2007	Ferrera
2007/0173757	A1	7/2007	Levine et al.
2007/0185524	A1	8/2007	Diaz et al.
2007/0225738	A1	9/2007	Pal
2007/0239193	A1	10/2007	Simon et al.
2007/0239199	A1	10/2007	Jayaraman
2007/0282425	A1	12/2007	Kleine et al.
2007/0299461	A1	12/2007	Elliott
2008/0045922	A1	2/2008	Cragg et al.
2008/0046092	A1	2/2008	Davis et al.
2008/0046093	A1	2/2008	Davis et al.
2008/0051803	A1	2/2008	Monjtadt et al.
2008/0097462	A1	4/2008	Mitelberg et al.
2008/0103585	A1	5/2008	Monstadt et al.
2008/0125855	A1	5/2008	Henkes et al.
2008/0228215	A1	9/2008	Strauss et al.
2008/0228216	A1	9/2008	Strauss et al.
2008/0300616	A1	12/2008	Que et al.
2008/0306504	A1	12/2008	Win et al.
2008/0319532	A1	12/2008	Monstadt et al.
2009/0048631	A1	2/2009	Bhatnagar et al.
2009/0069836	A1	3/2009	Labdag et al.
2009/0149864	A1	6/2009	Porter
2009/0182268	A1	7/2009	Thielen et al.
2009/0254111	A1	10/2009	Monstadt et al.
2009/0254169	A1	10/2009	Spenser et al.
2009/0270877	A1	10/2009	Johnson et al.
2009/0312748	A1	12/2009	Johnson et al.
2010/0004673	A1	1/2010	Denison et al.
2010/0004675	A1	1/2010	Wilson et al.
2010/0023105	A1	1/2010	Levy et al.
2010/0030200	A1	2/2010	Strauss et al.
2010/0030319	A1	2/2010	Weber
2010/0049165	A1	2/2010	Sutherland et al.
2010/0076479	A1	3/2010	Monstadt
2010/0174269	A1	7/2010	Tompkins et al.
2011/0022003	A1	1/2011	Tekulve
2011/0098814	A1	4/2011	Monstadt et al.
2011/0118777	A1	5/2011	Patterson et al.
2011/0172700	A1	7/2011	Bose et al.
2011/0184454	A1	7/2011	Barry et al.
2011/0213406	A1	9/2011	Aganon et al.
2011/0245861	A1	10/2011	Chen et al.
2011/0313447	A1	12/2011	Strauss et al.
2013/0190801	A1	7/2013	Divino et al.
2013/0253572	A1	9/2013	Molaei et al.

FOREIGN PATENT DOCUMENTS

CN	1668250	A	9/2005
DE	4445715		6/1996
DE	69627243		1/1997
DE	19547617		9/1997
DE	19607451		9/1997
DE	19610333		9/1997
DE	19647280		5/2001
DE	19952387		5/2001
DE	10010840		9/2001
DE	10118017		10/2002
DE	10155191		5/2003
EP	707830		4/1996
EP	711 532		5/1996
EP	717969	A2	6/1996
EP	720838		7/1996
EP	765636		4/1997
EP	792623		9/1997
EP	820726		1/1998
EP	829236		3/1998
EP	830873		3/1998
EP	853955		7/1998
EP	865773		9/1998
EP	882428		9/1998
EP	904737		3/1999
EP	914807		5/1999
EP	941700		9/1999
EP	941701		9/1999
EP	992220		4/2000
EP	1005837	A2	6/2000
EP	1120088		8/2001
EP	1125553		8/2001
EP	1129666		9/2001
EP	1142535		10/2001
EP	1169969		1/2002
EP	1188413		3/2002
EP	1188414		3/2002
EP	1295563		3/2003
EP	1312312		5/2003
EP	1316293		6/2003
EP	1358850		11/2003
EP	1374801		1/2004
EP	1669032		6/2006
EP	1738698	A2	1/2007
EP	832607		4/2008
EP	2260800	A2	12/2010
EP	2292147		3/2011
JP	6-246004		9/1994
JP	7-155331		6/1995
JP	7-265431		10/1995
JP	7-284534		10/1995
JP	9-168541	A	6/1997
JP	10-201766		8/1998
JP	11-47138		2/1999
JP	11-76249		3/1999
JP	2001-513389	A	9/2001
JP	2002-523172	A	7/2002
JP	2004-500929	A	1/2004
JP	2006-051349	A	2/2006
JP	2008-525113	A	7/2008
KR	10-2010-107255		10/2010
KR	10-1014547		2/2011
WO	WO-88/03817		6/1988
WO	WO-89/06984		8/1989
WO	WO-90/12616		11/1990
WO	WO-91/13592		9/1991
WO	WO-92/14408		9/1992
WO	WO-92/21400		12/1992
WO	WO-93/11719		6/1993
WO	WO-93/16650		9/1993
WO	WO-94/06502	A2	3/1994
WO	WO-94/06503		3/1994
WO	WO-94/10936		5/1994
WO	WO-94/11051		5/1994
WO	WO-94/26175		11/1994
WO	WO-95/12367		5/1995
WO	WO-96/18343		6/1996
WO	WO-96/32153		10/1996
WO	WO-96/39950		12/1996
WO	WO-97/27888		8/1997
WO	WO-97/42881		11/1997
WO	WO-98/09570		3/1998
WO	WO-98/17183		4/1998

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	WO-98/33452		8/1998
WO	WO-98/34546		8/1998
WO	WO-98/39048	A2	9/1998
WO	WO-98/58590		12/1998
WO	WO-99/02094		1/1999
WO	WO-99/05977		2/1999
WO	WO-99/07292		2/1999
WO	WO-99/09893		3/1999
WO	WO-99/32037		7/1999
WO	WO-99/42038		8/1999
WO	WO-99/44538		9/1999
WO	WO-99/49812	A2	10/1999
WO	WO-99/56636		11/1999
WO	WO-00/12016		3/2000
WO	WO-00/13593		3/2000
WO	WO-00/25680		5/2000
WO	WO-00/44306		8/2000
WO	WO-00/72781	A2	12/2000
WO	WO-01/32085		5/2001
WO	WO-01/45571	A1	6/2001
WO	WO-01/56500	A2	8/2001
WO	WO-01/58365		8/2001
WO	WO-01/58382	A2	8/2001
WO	WO-01/87184		11/2001
WO	WO-01/93937	A2	12/2001
WO	WO-02/02018		1/2002
WO	WO-02/13705		2/2002
WO	WO-02/13706	A2	2/2002
WO	WO-02/32496		4/2002
WO	WO-02/39911	A2	5/2002
WO	WO-02/41753	A2	5/2002
WO	WO-02/45596	A2	6/2002
WO	WO-02/054943	A2	7/2002
WO	WO-02/054980	A2	7/2002
WO	WO-02/072168	A2	9/2002
WO	WO-02/087449		11/2002
WO	WO-02/087651		11/2002
WO	WO-02/089676	A2	11/2002
WO	WO-02/096273	A2	12/2002
WO	WO-02/096301		12/2002
WO	WO-03/001970	A2	1/2003
WO	WO-03/007823		1/2003
WO	WO-03/017852		3/2003
WO	WO-03/034927		5/2003
WO	WO-03/039624	A2	5/2003
WO	WO-03/041615		5/2003
WO	WO-03/053257		7/2003
WO	WO-03/053281		7/2003
WO	WO-03/073914	A2	9/2003
WO	WO-03/077776		9/2003
WO	WO-03/077984		9/2003
WO	WO-03/082128		10/2003
WO	WO-03/086240		10/2003
WO	WO-03/092547		11/2003
WO	WO-03/099370		12/2003
WO	WO-2004/008974		1/2004
WO	WO-2004/010878	A1	2/2004
WO	WO-2004/014239		2/2004
WO	WO-2004/069059		8/2004
WO	WO-2004/073529		9/2004
WO	WO-2005/065556		7/2005
WO	WO-2006/058042	A2	6/2006
WO	WO-2006/069123		6/2006
WO	WO-2007/121405		10/2007
WO	WO-2008/112435		9/2008
WO	WO-2008/112436		9/2008
WO	WO-2008/127328		10/2008
WO	WO-2010/092174	A2	8/2010
WO	WO-2010/117883		10/2010
WO	WO-2010/123821		10/2010
WO	WO-2010/134914		11/2010
WO	WO-2011/030820		3/2011
WO	WO-2012/161953	A2	11/2012

* cited by examiner

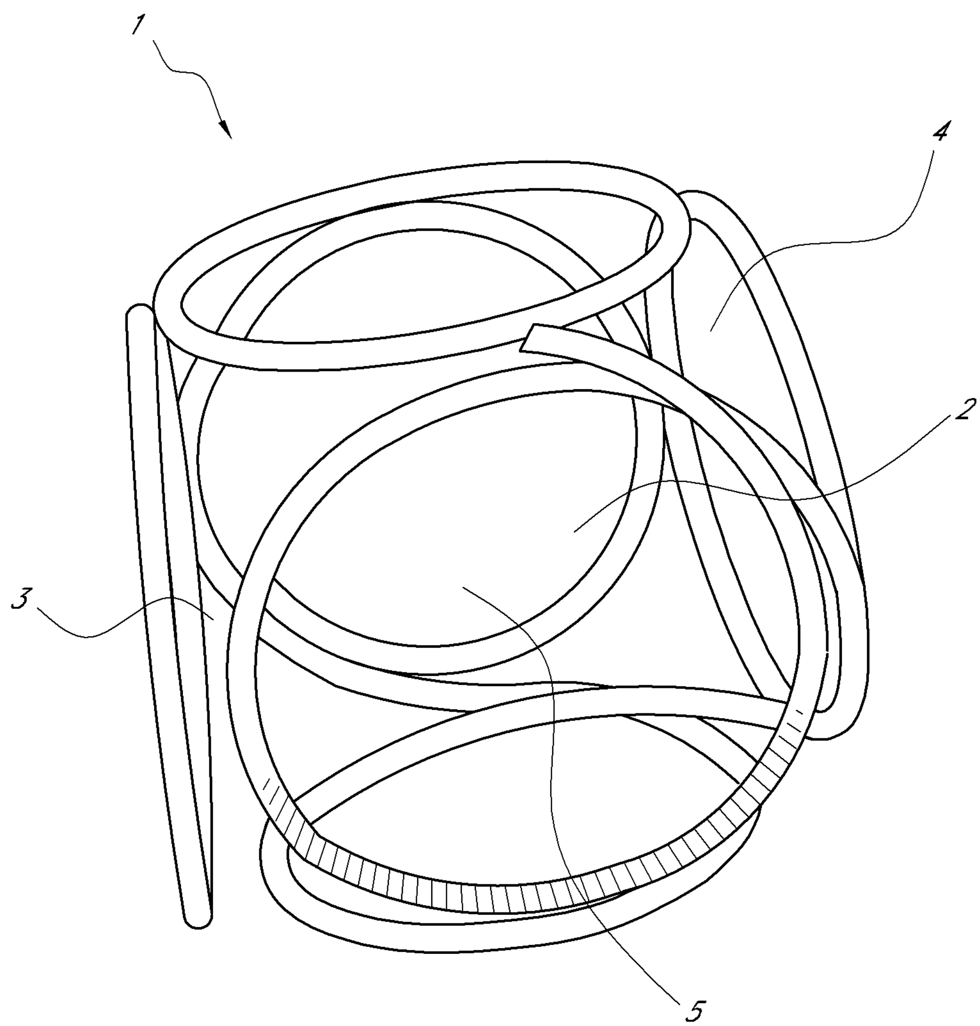


FIG. 1

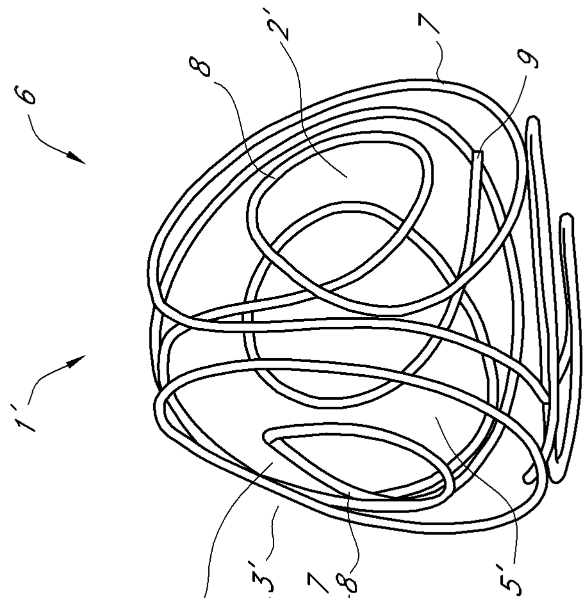


FIG. 2B

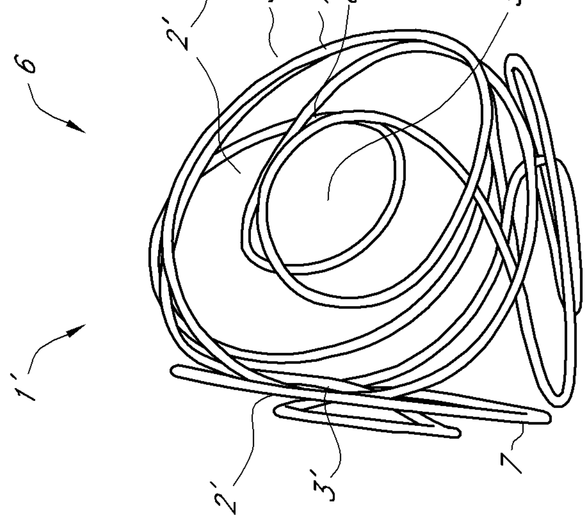


FIG. 2A

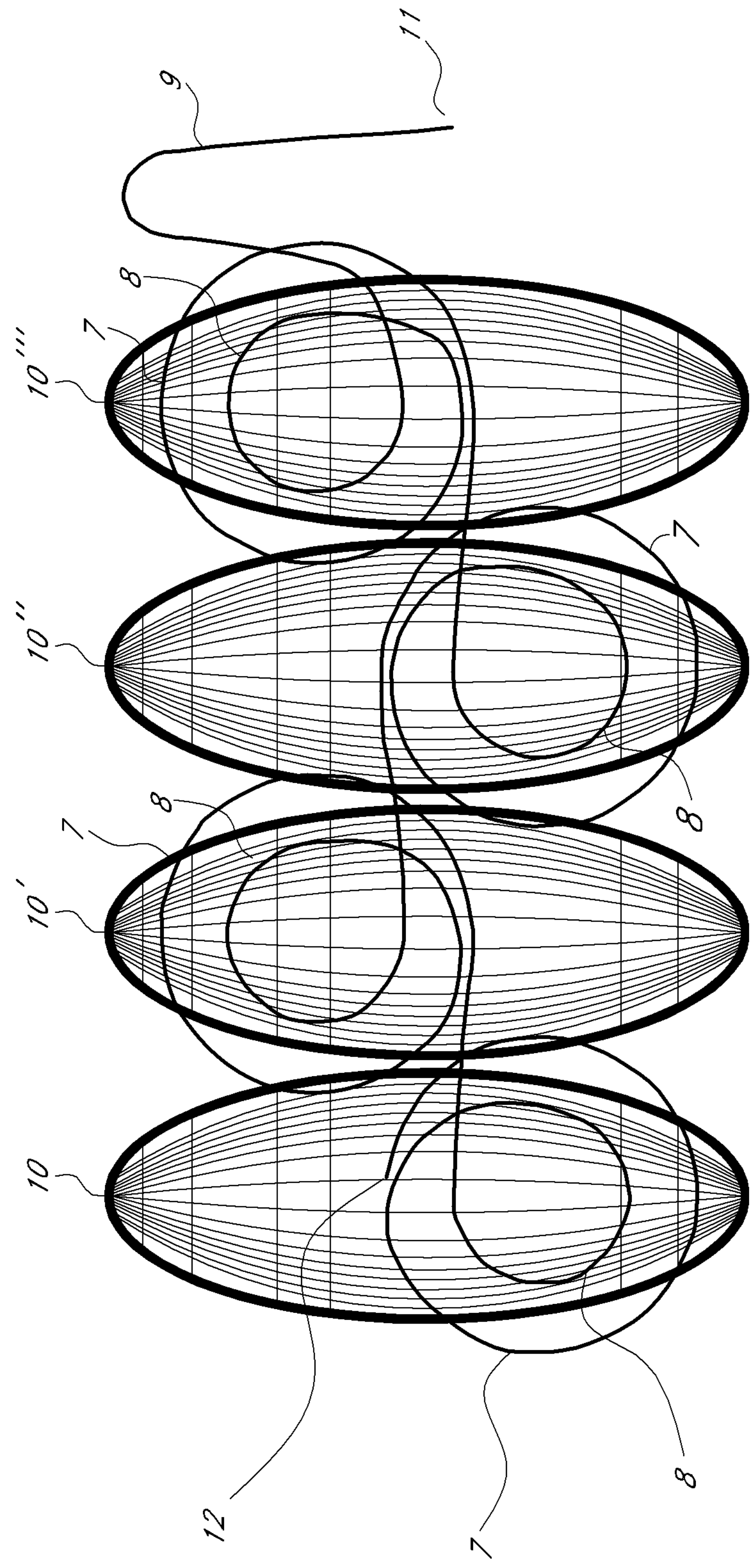


FIG. 3

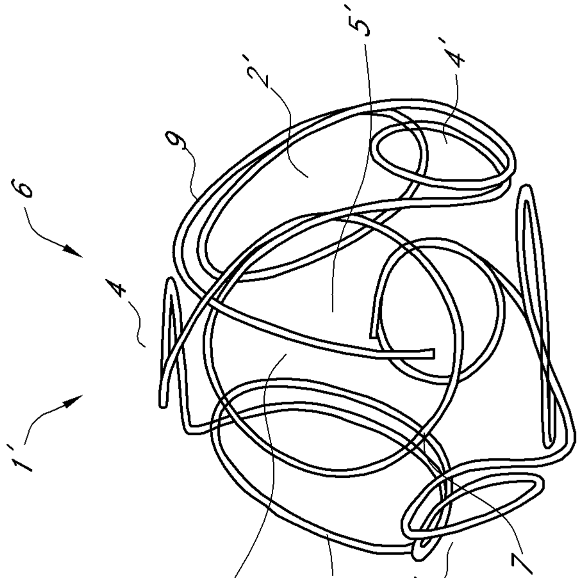


FIG. 4B

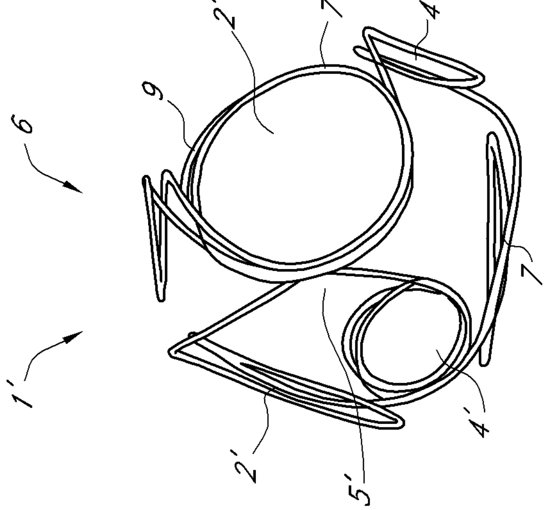


FIG. 4A

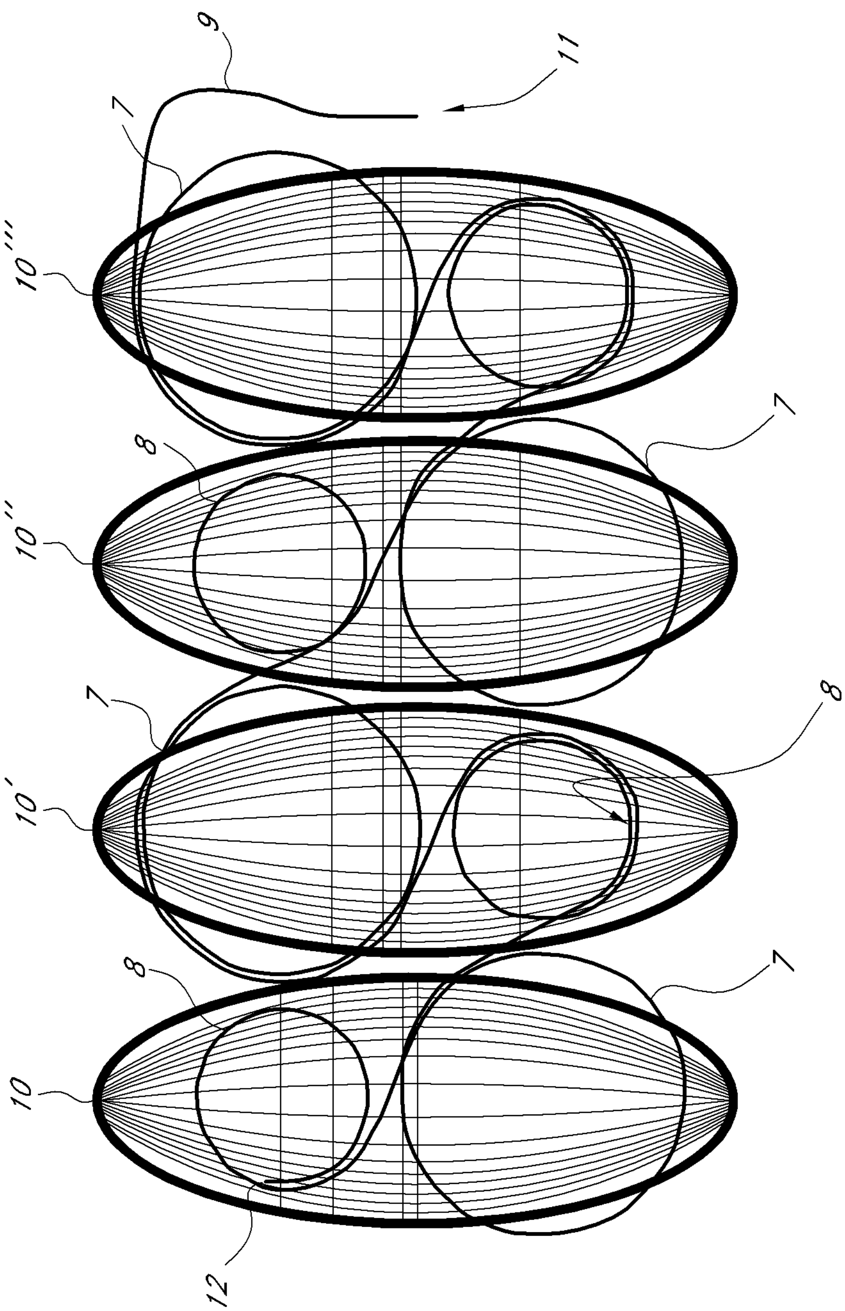


FIG. 5

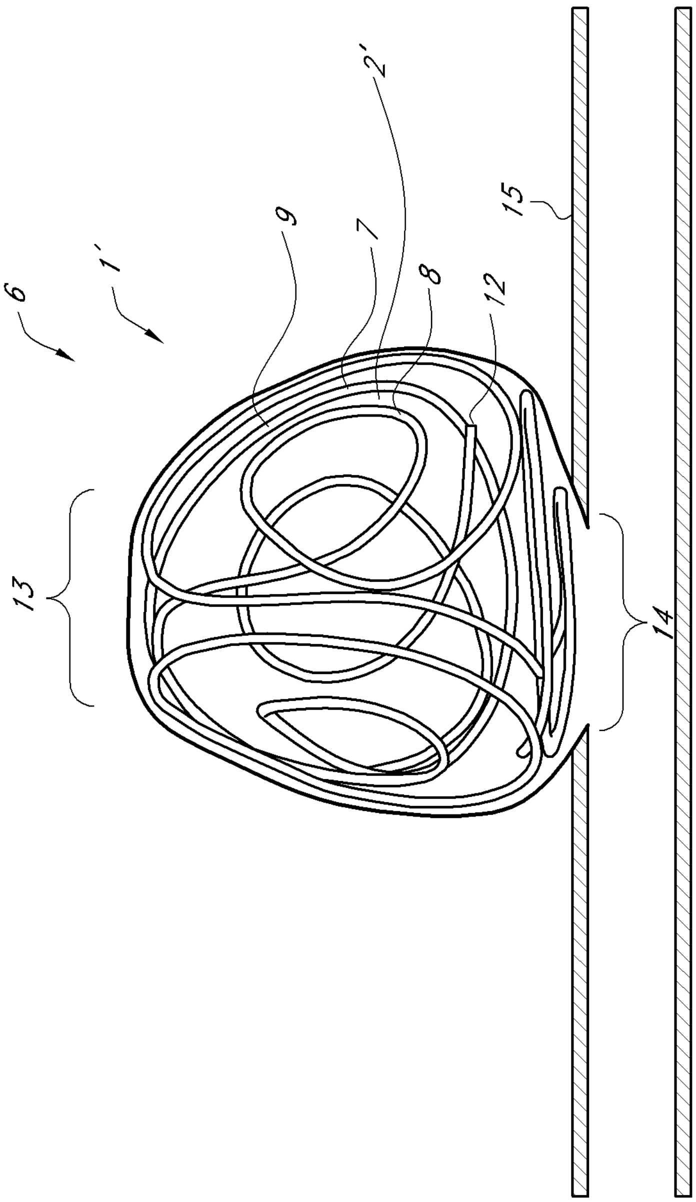


FIG. 6

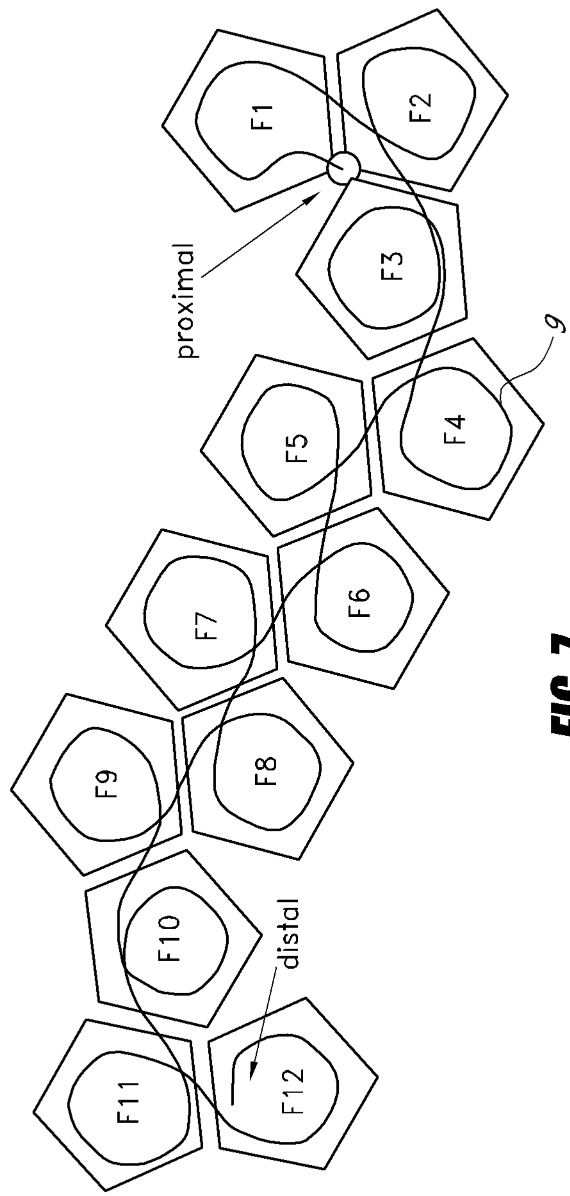


FIG. 7

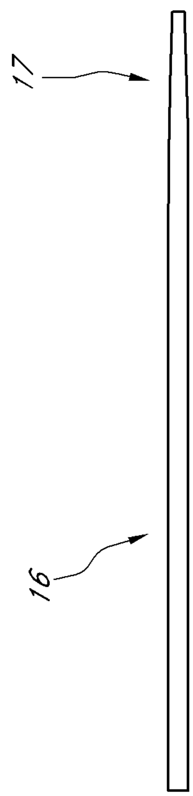


FIG. 8

MEDICAL IMPLANT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 12/981,286, filed Dec. 29, 2010, which is incorporated in its entirety by reference, herein, and which is a continuation of U.S. application Ser. No. 11/575,798, filed May 1, 2008, which is incorporated in its entirety by reference, herein, and which is a national phase application of International Application No. PCT/EP2004/010610, filed on Sep. 22, 2004 and published in German on Mar. 30, 2006 as WO 2006/032289 A1, which is incorporated in its entirety by reference, herein.

BACKGROUND

1. Field of the Invention

The invention relates to a medical implant in the form of an elongated helix wherein at least one part of the helix is preformed in such a manner that it has a secondary structure which it assumes during implantation at the placement site, with said structure in turn forming at the placement site during implantation a polyhedral tertiary structure, with each face of the polyhedron being built up by a loop.

The invention, furthermore, relates to a device for the implantation of such implants in body cavities and vessels.

2. Description of the Related Art

Known in the art is the use endovascular techniques for the occlusion of body cavities or vessels such as arteries, veins, fallopian tubes or vascular deformities such as, for example, vascular aneurysms. In this case, the closure element (also termed occlusion means) is usually introduced by means of an insertion aid through a catheter into the cavity to be occluded and deposited therein by means of one of various known techniques. The occlusion of the cavity finally is brought about by an embolus that forms as a result of the flow of blood slowing down in the cavity thus reduced in size or filled by the occlusion means.

It is furthermore known in the art to introduce a plurality of filamentous occlusion means, for the most part helixes or spirals of stainless steel or platinum alloys, into vascular aneurysms, with said means then assuming a random configuration and in this way occlude the aneurysm. The drawback of such a method is that the occlusion means often fill and stabilize the cavity only inadequately and it is quite difficult to foresee the behavior of said means when assuming their superimposed structures so that in the end the safety of the operation may be at risk as a 'stiletto effect' cannot be ruled out and may even entail wall ruptures.

SUMMARY OF THE INVENTION

In order to circumvent such disadvantages it is furthermore known to make use of occlusion means made of shape memory materials, said means assuming a defined secondary and/or tertiary structure when inserted into the cavity to be occluded.

With a view to most effectively filling vascular aneurysms and at the same time stabilizing the aneurysm wall it is thus known in this context from WO 01/93937 to use an occlusion means made of a material having shape memory properties, said means when inserted having the primary form of an elongated filament that upon being inserted into the aneurysm to be occluded develops into a secondary structure forming six loops of identical size which together build up a three-dimensional tertiary structure having the form of a cage or cube. Each of the loops thus forms a face of the spatial structure and in this way determines the size of the structure.

This principle is also known from WO 03/017852 which provides for implants that as soon as external constraints are removed assume a regular, meander-like secondary structure which in turn develops into a spatial tertiary structure taking for example the form of a geometric cage, cube, tetrahedron or prism.

Occlusion means of this kind are meant to stabilize the aneurysm wall so that further filamentous occlusion means can be inserted subsequently without running the risk of causing wall ruptures. Although such occlusion means may be viewed as an improvement compared to non-preformed occlusion means in that they provide increased safety of operation, imminent rupturing danger still exists however in areas of the aneurysm wall, in particular those adjacent to faces and vertices as well as edges of the polyhedrons, especially as a result of the occlusion helixes subsequently inserted into the aneurysm. Moreover, because of the largely openly configured tertiary structure of such occlusion means the subsequently inserted occlusion means or portions of such occlusion means can only be prevented from exiting through the neck of the aneurysm primarily in the case of small-neck aneurysms.

In view of the disadvantages associated with the state of the art it is thus the object of the invention to provide an implant that further reduces risks for patients when body cavities and vessels have to be occluded. Desirable characteristics in this context are an extensive and dense coverage of the wall of the aneurysm, close contact with the aneurysm wall, a reliable occlusion of the aneurysm neck and/or prevention of the 'stiletto effect'.

According to the invention this objective is reached by providing a medical implant of the kind first mentioned above which is characterized in that the polyhedron is provided with at least one additional loop.

The invention is based on findings proving that when a higher packing density of the polyhedron is achieved through the provision or arrangement of additional loops the wall rupturing risk diminishes without the maneuverability of the implant during placement being impaired significantly. Preferably, the additional loops have a slightly smaller diameter than the loops building up the faces of the polyhedron.

In this case, the implant is preformed in such a manner that it assumes the desired secondary and tertiary structure after it has been released from the constraints of the catheter. For this purpose, an elastic biasing force is imprinted on the helix, but at least on the portion that forms the polyhedron, in a manner known through prior art techniques. Therefore, not before an external (thermal or mechanical) constraint is omitted does the implant abandon its elongated structure and forms into its predetermined three-dimensional tertiary structure. Such a mechanical constraint, for example, may be exerted by the catheter or a retaining element embracing or being situated within the helix. The thermal constraint may, for instance, be imposed by temperature conditions prevailing in the catheter that differ from those encountered in the blood stream. Means and interrelations of this kind are sufficiently known to competent persons skilled in the art.

With aid of inventive implants preformed in the described manner it is possible to achieve a dense and gentle filling of the cavity to be occluded without the wall of the cavity having to serve as an abutment when the desired three-dimensional structure is formed, which is the case with non-preformed implants. The risk of causing wall ruptures can thus be minimized.

Especially suited for the creation of such an elastic biasing force are materials having shape memory characteristics or materials having superelastic properties which are capable of undergoing a temperature- or stress-induced martensitic transformation or a combination of both. Other materials lacking shape memory properties such as, for example, platinum alloys, especially platinum-iridium and platinum-tungsten alloys, also lend themselves to the formation of the inventive implants.

In this context the additional loop or further loops may be arranged in the polyhedron on one or several faces of the polyhedron. For example, one or also several smaller sized loop(s) may thus be arranged within a face of the polyhedron formed by a larger loop. This leads to a denser packing of the polyhedron faces and minimizes the risk of the adjacent vessel or aneurysm walls becoming ruptured through additionally inserted filamentous occlusion means. Furthermore, the neck of the aneurysm can be better occluded in this way so that there is lower risk that additionally inserted filamentous occlusion means may exit.

The additional loop or further loops may also be arranged on the edges of the polyhedron to enable the polyhedron edges to become more densely packed which yields the advantages referred to above with respect to adjacent aneurysm areas.

Moreover, the additional loop or further loops may be arranged in areas of the vertices of the polyhedron to enable these vertex locations to become more densely packed which also yields advantages as described hereinbefore with respect to adjacent aneurysm areas.

The three above elucidated possibilities of arranging further loops are not necessarily facultatively with embodiments featuring more than one additional loop but may also be adopted in a cumulative manner to create packings of the polyhedron that are optimally adapted to the cavity to be occluded. The objective in this way is to obliterate the neck of the aneurysm to prevent the spirals from being flushed out.

As per an expedient embodiment of the inventive implant the polyhedron is a regular or a semi-regular polyhedron. In the event of a semi-regular polyhedron the faces themselves are also built up by differently sized loops. Furthermore, loops of even smaller size may be arranged within the smaller polyhedron faces formed by smaller loops so that the relevant faces can be provided with a denser packing. The above described steps aimed at achieving a denser packing in the areas of vertices and/or edges may expediently be adopted in this case as well.

It is seen as particularly expedient here if the polyhedron is a tetrahedron, a hexahedron (preferably a cube), an octahedron, a dodecahedron or an icosahedron. In the framework of the present invention a tetrahedron is especially preferred.

The loops may be provided in the form of closed or open loops. In a closed loop the proximal and distal ends of the filament portion forming the closed loop intersect whereas such intersection or crossing does not take place in open loops. Because of the increased stability of the tertiary structure formed by the loops it is considered advantageous if at least one and preferably all of the loops are closed loops.

According to another preferred embodiment the size relation between small and large loops ranges between 1:1.1 and 1:5, preferably 1:1.1 and 1:4 and especially preferred 1:1.1 and 1:2. The sizing depends, inter alia, on the arrangement of the loops at the faces/edges or vertices. The implant in this case may consist of loops of two or more different sizes. If two loops are arranged on one face the size relation as a rule ranges between 1:1.1 and 1:2 with the diameter serving as reference dimension.

As per another preferred embodiment the implant comprises more than one smaller loop. Particularly preferred in the interest of increasing the safety of operations by providing a higher packing density is a numerical relation between smaller and larger loops of at least 1:1.

With a numerical relation between smaller and larger loops of 1:1 it is preferred if the small and large loops are alternately arranged along the linear extension of the filament. This arrangement results in the safety of the treatment being further enhanced because it greatly improves the maneuverability and, surprisingly, enables the implanted filament to be partially retracted from the cavity and into the catheter for repositioning purposes during placement without canting, knots or failure of the filament occurring.

In accordance with an especially preferred embodiment a smaller closed loop is arranged in the polyhedron in each of the polyhedron faces formed by the large loops.

It is, furthermore, particularly beneficial if in the polyhedron between each of two adjacent loops forming the faces at least one smaller loop each (or may be even more loops) is arranged. The loops arranged between each of two adjacent loops forming the faces of the polyhedron are situated on the edges of the polyhedron in this case.

Moreover, it is especially advantageous if in all areas of the polyhedron where in each case at least three the faces forming loops adjoin at least one small loop each is arranged (or may be even more loops). The loops arranged between each of at least three adjacent loops forming the faces of the polyhedron are situated on the vertices of the polyhedron in this case.

It is, moreover, particularly expedient if the polyhedron is a tetrahedron, the faces of which being formed by one of the large loops each, with one smaller loop being located in each larger loop in this case as well.

As per another preferred embodiment the polyhedron is a tetrahedron, the faces of which being formed by one of the large loops each, with one smaller loop being located between each of two large loops at one edge of the tetrahedron each.

A preferred further embodiment relates to an inventive medical implant wherein the polyhedron is a tetrahedron, the faces of which being formed by one of the large loops each, with one smaller loop being located between each of three large loops at one vertex of the tetrahedron.

For the purpose of occluding aneurysms it is seen particularly expedient to use implants according to the invention, the polyhedrons of which have a diameter ranging between 0.5 and 30, preferably 1 and 25 and especially preferred between 2 and 20 and in particular between 3 and 18 mm.

It is furthermore advantageous if the polyhedron is of larger size than the volume of the body cavity (the so-called "therapeutic space") for the filling of which it is meant. This so-called 'oversizing' serves to stabilize the implant in the cavity to be occluded and in this way prevents it from being displaced within or expelled in part or completely from the cavity. However, to prevent the thin-walled aneurysms from being ruptured it is nevertheless deemed expedient not to provide for too great a size of the polyhedron in relation to the relevant therapeutic space. It is therefore considered beneficial if the diameter of the polyhedron is not sized greater than 2.5, preferably 1.1 to 2 and especially preferred 1.2 to 1.5 times the diameter of the body cavity it shall fill.

The implant according to the invention is thus particularly suited for the occlusion of aneurysms having a therapeutic measure (that is a diameter) ranging between 0.4 and 40, preferably between 1.5 and 20 and in particular between 2 and 18 mm.

According to an expedient embodiment the filament (if only a portion of the filament is used to form the polyhedron than particularly this portion) in its extended state has a length of between 50 and 600 and preferably between 75 and 500 mm.

The inventive implant may comprise, for example, of a helix or spiral formed by means of at least a single wire or with the aid of a cable-like structure formed by means of at least two wires. Configurations in the form of a helix or spring or cable-like structure thus offer advantages in that an enlarged surface is provided for thrombozation purposes. To achieve the same purpose further configurations of the helix can be put to use that are conducive to a surface enlargement, for example providing said helix with fibers promoting the formation of thrombi.

The single or plurality of wires in this case expediently have a diameter ranging between 20 and 200, preferably between 30 and 100, especially preferred 50 and 70 and in particular between 55 and 65 .mu.m.

In accordance with an expedient embodiment the helix or spiral has an internal lumen that is closed off at least at the distal end. At the proximal end the lumen may be open or closed. A lumen open towards the proximal end is, for instance, expedient if a removable retaining element is arranged in the inner lumen of the filament, said element preventing the previously imprinted secondary and tertiary structure to be assumed as long as it is located inside the implant. Such a retaining element has been disclosed via publication WO 03/041615, with express reference being made here to its disclosure content.

It is, furthermore, expedient if the helix has an outer diameter of between 0.1 and 0.5, preferably between 0.2 and 0.35 and especially preferred between 0.24 and 0.28 mm. The helix in this case is preferably designed as micro-helix or micro-spring comprising one or several wires or as a cable-like structure consisting of more than one wire braided or twisted together.

As per a further expedient embodiment at least one of the wires forming the helix or the wire forming the helix is made of a platinum alloy, preferably a platinum-iridium or a platinum-tungsten alloy or a metal alloy having shape memory properties.

It may be expedient if a filamentous shaping element made of a metal alloy having shape memory properties passes through the helix along its longitudinal axis. The shaping element serves to bring about the secondary and tertiary structure of the implant having left the catheter. In this embodiment the filament having been released from the catheter adapts to the predetermined shape of the shaping element which enables the envisaged three-dimensional tertiary structure to be formed. Such a shaping element, for example, has been disclosed in publication WO 03/017852, with explicit reference being made here to its disclosure content.

This embodiment provides for the helix to be expediently designed as cable comprising several wires, one of which being the shaping element, and, especially preferred, as spiral or helix through which inner lumen the shaping element, preferably a wire, extends. It is, furthermore, considered expedient with this embodiment if the spiral or helix or, in case the design provides for a cable, those parts of the cable which do not form the shaping element, are made of a material that does not have shape memory properties. Particularly expedient in this case is a platinum-iridium alloy.

The alloy having shape memory properties in this case is preferably a titanium- and nickel-containing alloy (also known under the name of nitinol), an iron-based or copper-based alloy.

According to another preferred embodiment the filamentous shaping element extending along the longitudinal axis of the helix has a tapered portion situated in its distal end area. In this area said shaping element thus has a diameter smaller than the element diameter in proximal direction. Such a distal tapered portion causes the shaping element to be softer and less stiff so that traumatizing risks are less imminent in the event the distal end of the shaping element comes into contact with the wall of the aneurysm. Said distally arranged tapered section is provided because it was found that the total stiffness of a helix through which a filamentous shaping element extends is for the main part due to the shaping element and only to a lesser extent to the helix itself. The taper may, for example, extend from the distal tip over a length of approx. 20 mm and may have an incremental slope, but preferably a continuous slope. All in all, the diameter of the shaping element up to its distal tip preferably reduces to approx. 25 to 50% of the diameter existing in the remaining area.

Another expedient embodiment relates to an inventive medical implant wherein a filamentous retaining element made of a polymer material (in particular a polyester or polyamide) or a metal wire without shape memory properties (in particular a medical stainless steel wire) passes through the helix along its longitudinal axis. The retaining element in this case serves to maintain the elongated configuration (in this case the retaining element expediently is made and consists of a metal wire, especially in combination with a helix made of a shape memory material) or secure the helix preventing it from being torn off during placement, in particular when repositioning is required. In the latter case, provision of the retaining element made of a polymer material and of the helix made of a shape memory material or a platinum-tungsten alloy is deemed particularly expedient. Because of its good supporting qualities instrumental in improving the slidability of the implant using a platinum-tungsten alloy material for the helix is especially preferred.

The present invention, furthermore, relates to a device for the placement of implants into body vessels and cavities with an implant in accordance with the invention and an insertion aid which is detachably connected to the proximal end of the implant.

The insertion aid in this case is preferably designed as a guide wire which expediently and at least in part has the form of a helix or spring. The dimensioning and selection of suitable materials is sufficiently known to competent persons skilled in the art. For this purpose and by way of example explicit reference is made to the disclosure content of publications WO 03/017852 and WO 03/041615.

If the inventive implant is provided with a removable retaining element it has, expediently, the form of an open tube through which the retaining element can be introduced in and removed from the implant.

For the purpose of placing the implant into the cavity to be occluded implant and insertion aid are expediently connected with each other by means of a severance module. For electrolytic placement of the implant the severance module is expediently provided with an electrolytically corrodible spot made of a suitable material, for example a corrodible steel alloy.

Moreover, in the implant according to the invention one or more additional severance modules may be provided and arranged in the helix proximal to the portion forming the polyhedron. This enables the inner hollow space of the polyhedron to be filled immediately after it has been placed into the body cavity to be occluded. The filament segment arranged between polyhedron and severance module may be elastically preformed itself so that it is capable of assuming or taking up a defined form or position within the polyhedron. Arranging several severance modules of this kind inside the helix enables helix segments that can be variably sized to be introduced into the polyhedron lumen. For electrolytic placement of the implant the severance module is expediently provided with an electrolytically corrodible spot or location.

It is also viewed expedient if the device in accordance with the invention also comprises a catheter, a voltage source and a cathode, with the implant serving as anode and being longitudinally movable in the catheter, and with the connection between implant and insertion aid (preferably the severance module) having an electrolytically corrodible location so that the implant can be detached by electrolytic processes when in contact with a body fluid.

In the interest of high resistance against fracture or breaking and at the same time aiding the detachment process the severance module has a diameter ranging between 30 and 150, preferably between 40 and 120 and especially preferred between 50 and 100 .mu.m. The electrolytically corrodible location in this case may have a smaller diameter than the adjacent proximal and distal areas of the severance module (the severance module in this case tapers off towards the electrolytically corrodible spot).

The severance module is expediently provided with a proximal and a distal helix as well as a segment arranged in between, with the helixes consisting of a material whose susceptibility to electrolytic corrosion is lower than that of the interposed segment. Suitable and expedient material combinations are noble metals or noble metal alloys, preferably platinum or platinum alloys for the proximal helix or distal helix and stainless steel (e.g. grades AISI 301, 303 or 316 as well as subgroups thereof or N-alloyed austenitic steel of stainless quality grade, preferably from the group of pressure-nitrided steels) for the interposed segment. Material combinations of this type are also known from WO 03/017852 to which reference is made here.

In accordance with an advantageous embodiment of the inventive device the severance module is non-detachably connected to the implant and the insertion aid by welding, soldering, bonding or mechanical joining processes, particularly by force- or form-closing methods in a manner known to persons skilled in the art.

As per another advantageous configuration of the inventive device the insertion aid is surrounded, at least in part, by an electrically insulating shrunk-on sleeve or an electrically insulating coating.

Moreover, the purpose of the invention can be most beneficially accomplished with the aid of a helix, the loops of which forming the faces of a dodecahedron, in particular a regular pentagonal dodecahedron. Due to the plurality of faces—twelve altogether—a very dense coverage of the wall is achieved so that, as the case may be, even without additional loops the aneurysm wall can be widely covered and an extensive obliteration of the neck of the aneurysm be brought about.

The helix designed and preformed so as to yield the shape of a pentagonal dodecahedron thus forms a flexible skeleton covering and protecting the wall, with said skeleton being capable of accommodating and retaining further helixes serving occlusion purposes. In this case further loops often need no longer be arranged additionally on faces, edges or vertices. In this respect, measures promoting the sliding behavior aimed at counteracting patient traumatizing risks can largely be dispensed with.

Arranging the proximal end of the helix forming the pentagonal dodecahedron on a vertex or corner point was found to be particularly beneficial. Since the neck of the aneurysm is usually located within a face of the polyhedron this makes it difficult for the last-inserted portion of the helix to slip out of the neck and helps to prevent the helix from being flushed out which anyway is improbable due to the plurality of the faces, the close contact with the wall of the aneurysm and the strain that as a rule prevails inside the aneurysm. The distal end of the helix is preferably arranged in a face and is the point where the first loop starts; advantageously here is a mainly atraumatic supporting location on a side facing away from the neck of the aneurysm.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is now described by way of examples as follows with reference being made to the figures showing the respective embodiments.

FIG. **1** shows the enlarged representation of a cube-shaped implant **1** of the state of the art;

FIGS. **2***a* and **2***b* are the enlarged representations of an inventive implant **1'** with smaller closed-loops **8** arranged in the tetrahedron faces **2'**;

FIG. **3** is the enlarged representation of an inventive implant **1'** with smaller closed-loops **8** arranged in the tetrahedron faces **2'**, shown as development of a ball;

FIGS. **4***a* and **4***b* are the enlarged representations of an inventive implant **1'** with smaller closed-loops **8** arranged at the vertices **4'** of a tetrahedron **6**;

FIG. **5** is the enlarged schematic representation of an inventive implant **1'** with smaller closed-loops **8** arranged at the vertices **4'** of a tetrahedron **6**, shown as development of a ball;

FIG. **6** is the enlarged vertical section of the inventive implant **1'** positioned in an aciniform aneurysm **13**;

FIG. **7** is the schematic representation of a development of an inventive implant in the form of a pentagonal dodecahedron; and

FIG. **8** shows the taper provided in the distal end area of a filamentous shaping element.

DETAILED DESCRIPTION

FIG. **1** represents a cube-shaped implant **1** of enlarged size reflecting the state of the art. The open configuration, especially of the faces **2** and vertex areas **4**, but also of edges **3**, is to be seen as a weak point of such implants **1** because the aneurysm wall in contact with them is particularly prone to rupture. In addition, the insufficient packing density of the implant **1** in the vicinity of said areas **2**, **3** and **4** only prevents to a minor extent implants subsequently placed for the purpose of filling the inner hollow space **5** from being expelled again.

FIG. **2** shows two views **2***a* and **2***b* of a tetrahedron-shaped implant **1'** according to the invention, said implant having assumed its three-dimensional tetrahedral tertiary structure. The faces **2'** of tetrahedron **6** are built up by two uniformly sized large loops **7**, two of which in each case being adjacently positioned, with the projections of the large loops **7** extending into the space constituted by the sectional areas of two neighboring large loops **7** each forming the imaginary edges **3'** of tetrahedron **6**.

In each of faces **2'** a loop **8** of smaller size is arranged. By this arrangement the packing density of the tetrahedron **6** in the area of faces **2'** is increased, which significantly improves the safety against rupturing dangers to which the adjoining aneurysm wall is exposed when implant segments or further implants are subsequently inserted or placed. The high packing density thus achieved in faces **2'** moreover prevents in particular subsequently inserted implant segments or subsequently inserted additional implants meant to fill the inner hollow space **5'** from being forced out again through the neck of the aneurysm. For that reason the implant **1'** according to the invention is particularly suited as well to the therapeutic occlusion of wide-neck aneurysms the treatment of which, as is known, is especially difficult as a rule.

Besides, the arrangement of the smaller loops **8** slightly raised above the projection plane of the tetrahedron faces **2'** formed by the large loops **7** enables the implant **1'** to be particularly well secured in the aneurysm, with special reference in this context being made to FIG. **2***a*.

Filament **9** forming the tetrahedron **6** is a micro-helix having a diameter of 0.26 mm and consisting of a platinum-iridium wire which has a diameter of 60 .mu.m. A nitinol wire extends through the inner hollow space of the micro-helix, said wire being non-detachably connected at the proximal and distal end to filament **9** and due to its elastic biasing force imprinting on the helix **9** the tetrahedral tertiary structure after said helix has been released from the catheter.

FIG. **3** represents the secondary structure of the tetrahedron shown in FIG. **2** in the form of a development of a ball making use of 4 radial sections **10** to **10'''**. The loops **7**/**8** themselves are of roughly circular shape and having assumed their predetermined spatial configuration form a regular tetrahedron. Along the longitudinal axis of helix **9** the large **7** and the small loops **8** are arranged alternately, with the small loops **8** being placed inside the large loops **7** in the secondary structure. The proximal and the distal ends of filament **9** are identified by reference number **11** and, respectively, **12**.

FIG. **4** shows two views **4***a* and **4***b* of a tetrahedron-shaped implant **1'** according to the invention, said implant having assumed its three-dimensional tertiary structure. The faces **2'** of tetrahedron **6** are built up by uniformly sized large loops **7** of which two each are positioned adjacent to each other and thus form by way of their projections the imaginary edges **3'** of tetrahedron **6**. At the location where the projection of three adjoining large loops **7** each intersects there are the vertices **4'** of the tetrahedron, with one smaller sized loop **8** each being arranged at said vertices. Since the smaller loops **8** are arranged below the imaginary points of intersection the tetrahedron **6** in this case has a more rounded shape deviating from an ideal geometric tetrahedron shape. By this arrangement the packing density of the tetrahedron **6** in the area of vertices **4'** is increased, which significantly improves the safety against rupturing dangers to which the adjacent aneurysm wall is exposed when implant segments or further implants are subsequently inserted or placed. Aside from this, the rounded tetrahedral shape thus formed will more favorably adapt to the organic structure of aneurysm lumens to be filled than could be accomplished with an ideal geometric tetrahedron. The high packing density thus achieved at vertices **4'** moreover prevents in particular implant segments or additional implants subsequently inserted or placed for the purpose of filling the inner hollow space **5'** from being forced out again through the neck of the aneurysm.

The helix **9** forming the tetrahedron **6** is a micro-helix having a diameter of 0.26 mm and consisting of a platinum-iridium wire which has a diameter of 60 .mu.m. A polymer thread or a thread made of a nickel-titanium alloy extends through the inner hollow space of the micro-helix, with said thread being fixed at the proximal and distal end of the helix **9** and prevents the helix **9** from being torn off during the placement or repositioning. On the platinum-iridium wire an elastic biasing force has been imprinted which forces it into its preformed tetrahedral configuration as soon as the mechanical constraint caused by the catheter has been omitted. Although the platinum-iridium alloy used has no shape-memory properties it greatly improves the slidability of the helix during placement on account of its excellent supporting characteristics.

FIG. **5** by way of 4 radial sections **10** to **10'''** represents the secondary structure of the tetrahedron shown in FIG. **4** in the form of the development of a ball. The loops **7**/**8** themselves are of roughly circular shape and having assumed their predetermined spatial configuration form a regular tetrahedron. Along the longitudinal axis of helix **9** the large **7** and the small loops **8** are arranged alternately, with the small loops **8** being placed between the large loops **7**. The proximal and the distal ends of helix **9** are identified by reference number **11** and, respectively, **12**.

In FIG. **6** an implant **1'** according to the invention is illustrated that is placed into an aciniform aneurysm **13**, said implant forming into a tetrahedron **6** as tertiary structure. By arranging the smaller loops **8** in the area of the faces **2'** of the tetrahedron **6** built up by the large loops **7** a higher packing density of the tetrahedron faces **2'** is achieved. This not only reduces the danger of a wall rupture but also and in particular prevents additionally inserted implants (not shown here) from exiting through the neck of the aneurysm **14**. This configuration even enables aneurysms exhibiting medium-sized necks **14** as illustrated here to be occluded without having to employ stents. It is particularly expedient here if the implant **1'** as shown is positioned in such a way that one of the tightly packed face areas **2'** of the tetrahedron **6** is situated at or above the aneurysm neck **14**.

The tetrahedral tertiary structure is excellently suited for the occlusion of large aneurysms, for example of an aneurysm **13** as shown here having a therapeutic dimension of 10 min in diameter. Since the tetrahedron **6** has a diameter of 12 mm it secures itself firmly inside the aneurysm **13** during placement when forming into its tertiary structure such that the tension thus built up prevents it from slipping out of the aneurysm **13**. Such an “oversizing” offers advantages particularly for the treatment of wide-neck aneurysms because customary implants are not sufficiently secured inside of them to make sure they cannot exit or be expelled.

With the help of a micro-catheter the implant **1'** with the distal portion **12** of the helix **9** in front was moved through the blood vessel **15** into the aneurysm **13** where, when discharged from the catheter, it assumed the illustrated three-dimensional tertiary structure on account of a mixed stress- and temperature-induced martensitic transformation of the nitinol wire accommodated in the micro-helix **9** consisting of a platinum-iridium alloy. After checking the correct positioning under radiographic control by employing customary state-of-the-art methods the implant was detached electrolytically from the insertion aid designed in the form of a guide wire. For this purpose and with the aid of a source of electrical power a voltage was applied for a period of 0.1 to 20 minutes to the cathode positioned on the body surface and to the implant **1'** acting as anode and being placed in the aneurysm **13** to be occluded. Applying this voltage resulted in the implant **1'** becoming electrolytically detached due to electrolytic corrosion taking place at the electrolytically corrodible location in the severance module arranged between the guide wire and the filament **9**. Said severance module is of particularly robust design and has a relatively large diameter of 100 .mu.m to yield a high margin of safety preventing kinking or buckling when the implant **1** is positioned. Finally, the guide wire was retracted into the catheter and then removed from the system together with the catheter.

FIG. **7** is a schematic view of the development of a pentagonal dodecahedron and the extension of a micro-helix **9** designed to form into a pentagonal dodecahedron. The individual faces F1 to F12 of the polyhedron are defined by the loops of the micro-helix. In this case the distal end of the micro-helix **9** is located on a face F12 whereas the proximal end enters the body at a vertex or corner point between F1/F2/F3.

FIG. **8** eventually shows as schematic representation the tapered portion of the distal end **17** of a filamentous shaping element **16** reducing to approx. 50% of the diameter.

What is claimed is:

1. A method of manufacturing a three-dimensional medical implant comprising:

attaching an elongated helix on a ball forming structure, the ball forming structure comprising at least four radial sections configured for forming loops;

forming at least one part of the helix to define a secondary structure comprising a first face loop, a second face loop, a third lace loop and a fourth face loop, the first, second, third and fourth face loops of substantially identical size,

biasing said secondary structure to form a polyhedral tertiary structure, the polyhedral tertiary structure comprising a polyhedron, wherein the faces of the polyhedron are built up by the first face loop, the second lace loop, the third face loop and the fourth face loop; and

forming at least one additional loop disposed on one of the groups consisting of (a) a polyhedron face and coplanar to the plane of at least one face loop, (b) polyhedron edge, and (c) a polyhedron vertex, the at least one additional loop configured for reducing the risk of tissue damage at the placement site,

wherein the at least one additional loop is smaller than the first face loop.

2. The method according to claim **1**, wherein the polyhedron is selected from the group consisting of a tetrahedron, a hexahedron, an octahedron, a dodecahedron, a pentagonal dodecahedron, and an icosahedron.

3. The method according to claim **1**, wherein the at least one additional loop is a closed loop.

4. The method according to claim **1**, further comprising forming multiple additional loops coplanar to the plane of at least one of the first, second and third loops of the polyhedron, wherein each additional loop is smaller than its corresponding larger face loop forming the polyhedron face.

5. The method according to claim **1**, wherein the face loops are closed loops alternately arranged in a linear extension of the elongated helix.

6. The method according to claim **1**, wherein the elongated helix has an outside diameter ranging between 0.1 and 0.5 mm.

7. The method according to claim **1**, wherein at least one of the wires forming the elongated helix comprises one of a platinum-iridium and platinum-tungsten alloy having shape memory properties.

8. The method according to claim **1**, further comprising temporarily attaching said elongated helix to at least one severance module provided with an electrolytically corrodible location which is arranged in the elongated helix proximally to a portion thereof forming the polyhedron.

9. The method according to claim **1**, further comprising:

inserting said elongated helix in a catheter; and

attaching said elongated helix to an insertion aid which is detachably connected to a proximal end of the implant.

10. A method of manufacturing a three-dimensional medical implant comprising:

attaching an elongated helix on a ball forming structure, the ball forming structure comprising at least four radial sections configured for forming loops;

forming at least one part of the helix to define a secondary structure comprising at least four face loops of substantially identical size,

biasing said secondary structure to form a polyhedral tertiary structure, the polyhedral tertiary structure comprising a polyhedron, wherein the at least four loops establish faces of the polyhedron; and

forming at least one additional loop disposed on one of the groups consisting of (a) a polyhedron face and coplanar with the polyhedron face, (b) polyhedron edge, and (c) a polyhedron vertex, the at least one additional loop configured for reducing the risk of tissue damage at the placement site,

wherein the at least one additional loop is smaller than the at least four face loops.

11. The method according to claim **10**, wherein the polyhedron is selected from the group consisting of a tetrahedron, a hexahedron, an octahedron, a dodecahedron, a pentagonal dodecahedron, and an icosahedron.

12. The method according to claim **10**, wherein the at least one additional loop is a closed loop.

13. The method according to claim **10**, further comprising forming multiple additional loops coplanar to the plane of at least one of the face loops of the polyhedron, wherein each additional loop is smaller than its corresponding larger face loop forming the polyhedron face.

14. The method according to claim **10**, wherein the face loops are closed loops alternately arranged in a linear extension of the elongated helix.

15. The method according to claim **10**, wherein the elongated helix has an outside diameter ranging between 0.1 and 0.5 mm.

16. The method according to claim **10**, wherein at least one of the wires forming the elongated helix comprises one of a platinum-iridium and platinum-tungsten alloy having shape memory properties.

17. The method according to claim **10**, further comprising temporarily attaching said elongated helix to at least one severance module provided with an electrolytically corrodible location which is arranged in the elongated helix proximally to a portion thereof forming the polyhedron.

18. The method according to claim **10**, wherein face loops and smaller additional loops are formed in a numerical proportion of approximately 1:1.

19. The method according to claim **10**, wherein at least one additional loop is formed in the polyhedron between two adjacent large loops.

20. The method according to claim **10**, wherein at least one additional loop is formed in the polyhedron between three adjacent large loops.

* * * * *